

EXHIBIT 7

[Home](#) [Inspections, Compliance, Enforcement, and Criminal Investigations](#) [Compliance Actions and Activities](#) [Warning Letters](#) [2012](#)

Inspections, Compliance, Enforcement, and Criminal Investigations

Chung's and Son Company 3/19/12



Department of Health and Human Services

Public Health Service
Food and Drug Administration
Baltimore District Office
Central Region
6000 Metro Drive, Suite 101
Baltimore, MD 21216
Telephone: (410) 779-6466
Fax: (410) 779-6706

WARNING LETTER CMS# 274400

March 19, 2012

CERTIFIED MAIL RETURN RECEIPT REQUESTED

Mr. Kwok K. Lee, Co-owner
Chung's and Son Company
4568 Beech Road
Temple Hills, MD 20748-6704

Dear Mr. Lee:

We inspected your seafood processing facility, located at 4568 Beech Road, Temple Hills, MD 20748-6704 on December 15, 19, 22 and 30, 2011. We found that you have serious violations of the seafood Hazard Analysis and Critical Control Point (HACCP) regulation, Title 21, Code of Federal Regulations, Part 123 (21 CFR Part 123), and the Current Good Manufacturing Practice regulation for foods, Title 21, Code of Federal Regulations, Part 110 (21 CFR Part 110). In accordance with 21 CFR 123.6(g), failure of a processor of fish or fishery products to have and implement a HACCP plan that complies with this section or otherwise operate in accordance with the requirements of Part 123, renders the fish or fishery products adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 342(a)(4). Accordingly, your vegetable and shrimp egg roll is adulterated, in that it has been prepared, packed, or held under insanitary conditions whereby it may have been rendered injurious to health. You may find the Act, the seafood HACCP regulation and the Fish and Fisheries Products Hazards & Controls Guidance through links in FDA's home page at www.fda.gov¹.

Additionally, our review of the labeling for your Vegetable Egg Roll and Shrimp Egg Roll products revealed that these products are misbranded within the meaning of Section 403 of the Act [21 U.S.C. §343] and the regulations for food labeling at Title 21, Code of Federal Regulations, Part 101 (21 CFR 101). You can find the Act and the FDA regulations through links in FDA's homepage at www.fda.gov².

Your significant violations were as follows:

Seafood HACCP Violations

1. You must conduct or have conducted for you a hazard analysis for each kind of fish and fishery product that you produce to determine whether there are food safety hazards that are reasonably likely to occur and you must have and implement a written HACCP plan to control any food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6 (a) and (b). However, your firm does not have a HACCP plan for your ready-to-eat shrimp egg rolls to control the food safety hazards of pathogen growth and potential toxin formation; pathogen survival through cooking; undeclared allergens or food intolerance substances; and metal inclusion.
2. You must monitor sanitation conditions and practices during processing with sufficient frequency to ensure compliance with current good manufacturing practice requirements in 21 CFR Part 110, to comply with 21 CFR 123.11(b). However, your firm did not monitor conditions and cleanliness of food contact surfaces, prevention of cross-contamination from insanitary objects, protection of food, food packaging material, and food contact surfaces from adulteration.
 - a. Cooked shrimp were cooled in a bucket with holes in its sides placed in a sink that was holding the water being used to cool the shrimp and no draining.
 - b. A container with holes in its sides holding cooked shrimp was placed directly in to a plastic container that was holding a brown-colored liquid from the previously thawed batch of shrimp that was held in the plastic container.

Misbranding

3. Your Shrimp Egg Roll product is misbranded within the meaning of Section 403(w) of the Act [21 U.S.C. 343(w)] in that the product fails to declare completely or accurately the known major food allergen shrimp as specified by the Act.

Section 201(qq) of the Act [21 U.S.C. § 321(qq)] defines as "major food allergens" milk, egg, fish, Crustacean shellfish, tree nuts, wheat, peanuts and soybeans, as well as any food ingredient that contains protein derived from one of these foods, with the exception of highly refined oils or ingredients derived from such oils. A food is misbranded if it is not a raw agricultural commodity and it is, or it contains an ingredient that bears or contains, a major food allergen, unless either:

- The word "Contains", followed by the name of the food source from which the major food allergen is derived, is printed immediately after or adjacent to the list of ingredients [Section 403(w)(1)(A) of the Act; 21 U.S.C. § 343(w)(1)(A)], or
- The common or usual name of the major food allergen in the list of ingredients is followed in parentheses by the name of the food source from which the major food allergen is derived (e.g., "Whey (milk)"), except that the name of the food source is not required when either the common or usual name of the ingredients uses the name of the food source or the name of the food source from which the major food allergen is derived appears elsewhere in the ingredient list (unless the name of the food source that appears elsewhere in the ingredient list appears as part of the name of a food ingredient that is not a major food allergen by definition) Section 403(w)(1)(B) of the Act [21 U.S.C. § 343(w)(1)(B)].

Further guidance and information on food allergens can be accessed on FDA's website at

<http://www.fda.gov/Food/LabelingNutrition/FoodAllergensLabeling/default.htm>³.

4. Your Vegetable Egg Roll and Shrimp Egg Roll products are misbranded within the meaning of Section 403(i)(2) of the Act [21 U.S.C. § 343(i)(2)] because they are fabricated from two or more ingredients, and the labels fail to declare the common or usual name of each ingredient as required by

21 CFR 101.4(b). For example:

- You fail to declare shrimp in the ingredient statement for your Shrimp Egg Roll product.
- The statement "fried in vegetable oil" is not provided for in 21 CFR 101.4." Fat and/or oil ingredients must be declared in accordance with 21 CFR 101.4(b)(14).
- The Vegetable Egg Roll product contain vermicelli rice noodles; however, neither this ingredient nor its sub ingredients are declared in the ingredient statement.
- The term "egg wash" is not an appropriate common or usual name. In addition, the sub ingredients of this multi-component ingredient are not declared.

The requirement to list these component ingredients (or "sub-ingredients") may be met by either parenthetically listing the component ingredients after the common or usual name of the main ingredient, or by listing the component ingredients without listing the ingredient itself. Under the first alternative, the component ingredients must be listed in descending order of predominance within the multi-component ingredient; and under the second alternative, the component ingredients must be listed in descending order of predominance in the finished food.

5. Your Vegetable Egg Roll and Shrimp Egg Roll products are adulterated within the meaning of section 402(c) of the Act [21 U.S.C. § 342(c)] because the products bear or contain a color additive which is unsafe within the meaning of section 721(a) of the Act [21 USC 379(a)]. Section 721(a) deems a color additive to be unsafe unless its use is in conformity with the color additive's listing regulation. Specifically, the listing regulation for FD&C Yellow No. 5 requires that the color additive be listed by that name in the ingredient list on the labels of foods for human use [21 CFR 74.705(d)(2)]. Your product is manufactured with an egg roll wrapper which contains FD&C Yellow #5; however, the label for the finished products fails to declare the presence of FD&C Yellow #5 in the ingredient statements.

6. Your Vegetable and Shrimp Eggs Rolls products are misbranded within the meaning of section 403(k) of the Act [21 U.S.C. § 343(k)] because the products bear or contain an artificial flavoring, coloring, or chemical preservative. In accordance with 21 CFR 101.22(k), the label of a food to which any coloring has been added shall declare the coloring in the statement of ingredients. Your products are manufactured with an egg roll wrapper which contains certified color additive FD&C Yellow #5 and FD&C Yellow #6; however, neither product bears a label identifying the presence of these color additives. Under 21 CFR 101.22(k)(1), certified colors must be declared by the name of the color additive listed in the applicable regulation in part 74 of part 82 of this chapter. The common or usual name may be abbreviated to omit the "FD&C" prefix and the term "No." (e.g., Yellow 5).

Additionally, in accordance with 21 CFR 101.22(j), the label of a food to which a chemical preservative has been added shall bear a declaration of both the common or usual name of the ingredient and a separate description of its function, e.g. "preservative", "to retard spoilage", "a mold inhibitor", "to help protect flavor" or "to promote color retention". The ingredient statement for your Vegetable Egg Roll and Shrimp Egg Roll products declares the presence of potassium sorbate, but fail to provide a separate description of the function of this ingredient as required.

We also note the following comments about your product labels:

- The raw shrimp used in your Shrimp Egg Roll product declares sodium tripolyphosphate, sodium acid pyrophosphate, sodium polyphosphate, sodium bisulfite and calcium chloride as ingredient; however you fail to list those sub-ingredients on your finished product label. Ingredients must be declared on the labels unless they are present in insignificant levels and do have a technical effect in the finished products. In addition, if these ingredients are functional as preservatives they must be declared in accordance with 21 CFR 101.22(j).
- It appears that you are using the same labeling for both your Vegetable and Egg Roll products by including the phrase "Shrimp or Vermicelli" adjacent to the "Egg roll ingredients" declaration and stamping the cartons with the words "Shrimp" or "Vegetable." If this is intended to be some sort of "Catch all" Or "Shotgun" labeling, it is not in accordance with the policy as explained in CPG Sec. 505.100.
- The carton label only provides a numeric count. As required by 21 CFR 101.105(c), when the declaration of quantity of contents by numerical count does not give adequate information as to the quantity of food in the package, it shall be combined with such statement of weight, measure, or size of the individual units of the foods which will provide such information. Count is not sufficient because the weight can vary. The net quantity of contents must include the net weight.
- The manufacturer's information on the product cartons does not include the street address in accordance with 21 CFR 101.5(d).
- Your product labels contain information in two languages. In accordance with 21 CFR 101.15(c)(2), if a product label contains any representation in a foreign language or foreign characters, all words, statements, and other information required by or under authority of the Act to appear on the label must appear in the foreign language. For additional information on General Food Labeling requirements go to <http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabelingNutrition/FoodLabelingGuide/default.htm>⁴.

We acknowledge your response dated January 14, 2012 to the Form FDA-483, Inspectional Observations, issued December 30, 2011. We have evaluate your response and found it to be inadequate because a HACCP plan has not been developed and implemented.

We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your product(s) and/or enjoin your firm from operating.

You should respond in writing within fifteen (15) working days from your receipt of this letter. Your response should outline the specific things you are doing to correct these violations. You should include in your response documentation such as HACCP and verification records, or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, you should explain the reason for your delay and state when you will correct any remaining violations.

This letter may not list all the violations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the seafood HACCP regulation (21 CFR Part 123) and the Current Good Manufacturing Practice regulation (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations.

Please send your reply to the U.S. Food and Drug Administration, Attention: Evelyn Bonnin, District Director, 6000 Metro Drive, Suite 101, Baltimore, MD 21215. If you have questions regarding any issues in this letter, please contact Ms. Kristy Leslie at (757) 483-7042.

Sincerely,

/S/
Evelyn Bonnin
District Director
Baltimore District

Close Out Letter

- [Chung's and Son Company - Close Out Letter 01/10/2013](#)⁵

Page Last Updated: 01/22/2013

Note: If you need help accessing information in different file formats, see [Instructions for Downloading Viewers and Players](#).

[Accessibility Contact](#) [FDA Careers](#) [FDA Basics](#) [FOIA No Fear Act](#) [Site Map](#) [Transparency Website Policies](#)

U.S. Food and Drug Administration
10903 New Hampshire Avenue

Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
[Contact FDA](#)



[For Government](#) [For Press](#)

[Combination Products](#) [Advisory Committees](#) [Science & Research](#) [Regulatory Information](#) [Safety](#) [Emergency](#) [Preparedness](#) [International Programs](#)
[News & Events](#) [Training and Continuing Education](#) [Inspections/Compliance](#) [State & Local Officials](#) [Consumers](#) [Industry](#) [Health Professionals](#) [FDA Archive](#)



U.S. Department of **Health & Human Services**

Links on this page:

1. <http://www.fda.gov>
2. <http://www.fda.gov>
3. <http://www.fda.gov/Food/LabelingNutrition/FoodAllergensLabeling/default.htm>
4. <http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/Food>
5. [/ICECI/EnforcementActions/WarningLetters/ucm336183.htm](http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm336183.htm)